

REMARKS/ARGUMENT

Claims 1-50 were presented to the Examiner for examination either as originally filed or as added in two previous amendments before first action. Dependent Claim 21 has been renumbered Claim 41, and miss numbered Claims 22-41 have been renumbered as Claims 21-40 by the Examiner. Claims 51-90 have been added. The specification has been amended to improve the grammar and accuracy of the language. No new matter has been added. Thus, Claims 1-90 are now presented in the application. Claims 17-90 are presented to the Examiner for examination. Consideration of Claims 51-90 are submitted to the Examiner as being allowable over each of the references cited and applied, whether taken alone or in combination with each other. Consideration of all of the claims presented in view of the prior art is respectfully requested.

Additionally, the Examiner has required restriction between two independent and distinct inventions represented by (1) Claims 1-16, drawn to an isotopic identification array, and (2) Claims 17-50, drawn to an isotopic identification method. Applicant has provisionally elected to prosecute Claims 17-50 in this application. Applicant acknowledges this election and the withdrawal from consideration of Claims 1-16 under 37 CFR §1.142(b) as being drawn to a non-elected invention.

Applicant however respectfully traverses the requirement for restriction as Claims 1-16 have been amended to be directed to the same invention as Claims 17-50, specifically Claims 42-44. The identification for a batched product claimed in Claims 1-16, 42-44, 51, 52, 55-69, and 71-72 is the same identification utilized in the method of Claims 17-41, 45-50, 53-54, 70, and 73-90. All of these claims should be in the same application.

Reconsideration of Claims 17-22, 24-33, and 41-50, rejected under 35 U.S.C. §102(b) as

being anticipated by the patent issued to Welle, is respectfully requested. Reconsideration of Claims 23, 24, and 34-40, rejected under 35 U.S.C. §103 as being unpatentable over Welle in view of Brand et al, is also respectfully requested. Finally, consideration of Claims 17-90 in view of the patents issued to Welle, Brand et al and each of the other references cited but not applied by the Examiner, whether taken alone or in combination with each other is also respectfully requested.

The patent issued to Welle does not teach or even suggest Applicant's method as claimed in Claims 17, 45, 50, or 70-74:

"17. The method of identifying batched products comprising the steps of analyzing said product for the concentration of a plurality of the naturally occurring stable isotopes of said product, arranging said concentrations of said isotopes into a mathematical array, formulating said mathematical array into a readable form, assembling product information, indexing said product information and said readable form thereby forming an index, and maintaining said index and said product information."

"45. A method of providing an objective identification of a batched product comprising the steps of analyzing a plurality of naturally occurring stable isotopes of said batched product, deriving empirical information from said analyzing step, and arranging said empirical information into a numerical array."

"50. A method for identifying a composition comprising identifying a plurality of the naturally occurring stable isotopes of said composition, analyzing said composition for the concentrations of a plurality of naturally occurring stable isotopes of said composition, deriving empirical information from said analyzing step, arranging said empirical information into a numerical array and formulating said numerical array into a readable form."

"70. A method of providing an objective identification of a batched product comprising the steps of analyzing a batched product for the concentration of a plurality of the naturally occurring stable isotopes of said batched product, arranging said concentrations of said isotopes into a mathematical array, formulating said mathematical array into a readable form,

assembling product information with regard to said batched product, indexing said product information and said readable form to a description of said product thereby forming an index, and maintaining said index and said product information and said readable form.

“71. An identification for a batched product comprising an arrangement of empirical information derived from an analysis of a plurality of naturally occurring stable isotopes of said batched product, said arrangement comprising a numerical array of said empirical information in readable form.”

“72. An identification for a batched product comprising an empirical information derived from an analysis of a plurality of naturally occurring stable isotopes of said batched product, said empirical information being arranged in a numerical array, said array being a readable form, said readable form being comparable to the empirical information of said naturally occurring isotopes of unknown products, said readable form being indexed to stored product information, whereby unknown products can be identified with and differentiated from said known products.”

“73. A method of linking an unknown composition to known compositions comprising the steps of analyzing a plurality of stable naturally occurring isotopes of a plurality of known compositions, deriving empirical information from said analyzing step of said known compositions, arranging said empirical information from said known compositions into numerical arrays, placing said numerical arrays and product of said known compositions into an index, analyzing a plurality of stable naturally occurring isotopes of an unknown composition, deriving empirical information from said analyzing step performed on said unknown composition, arranging said empirical information from said unknown composition into a numerical array, comparing said numerical array of said unknown composition to said numerical arrays of said index, determining whether said numerical array of said unknown composition matches any of the numerical arrays of said index.”

“74. A method of comparing batched products comprising the steps of analyzing a first plurality of stable naturally occurring isotopes of a second plurality of elements of a third plurality of batched products thereby generating a fourth plurality of isotopic data, said fourth plurality of isotopic data being for each of said third plurality of batched products, respectively, listing said fourth plurality of isotopic data, listing identifications of said third

plurality of batched products from which each of said fourth plurality of isotopic data were derived, linking said identifications with said isotopic data thereby forming an index, analyzing a fifth plurality of stable naturally occurring isotopes of a sixth plurality of elements of an unknown batched product thereby generating a seventh plurality of isotopic data, comparing said seventh plurality of isotopic data with said fourth plurality of isotopic data to identify said unknown product as one of said third plurality of batched products or to distinguish said unknown product from said third plurality of batched products, said fifth, sixth, and seventh plurality being less or equal in number to said first, second, fourth plurality, respectively, and determining the precision of said comparing step by selecting said fifth plurality of stable naturally occurring isotopes of said unknown product.”

In contrast, the patent issued to Welle discloses a method for identifying materials using an isotopic taggant composition and a taggant composition for retrospective identification of materials using controlled abundance ratios of multiple isotopes in each of one or more elements of the taggant composition. The taggant composition is proposed to comprise multiple taggant elements, with each of the taggant elements containing two or more stable isotopes presented in a selected artificial abundance ratio corresponding to an identification code. Nothing could be further from the method of Applicant.

Of all of the known elements known to man, many of these elements can be found in nature in the form of multiple isotopes. Of all of the isotopes known, there are two well defined groups of isotopes. The first of these groups of isotopes are known as radioactive or unstable isotopes inasmuch as they have finite half-lives and degenerate over time. The other well defined group of isotopes is stable isotopes, or non-radioactive isotopes (isotopes having an infinite half-life). The abundance of these isotopes is the same today as they were at the origin of the universe. Neither the patent issued to Welle nor Applicant’s invention utilizes radioactive isotopes. These isotopes cannot be used for product identification as these isotopes degrade over

time and are not in the same concentration today as they are tomorrow.

The patent issued to Welle and Applicant's invention are representative of the two well defined and different ways of retrospectively identifying products utilizing stable, non-radioactive isotopes, i.e., respectively, "tagging" and "fingerprinting." The patent issued to Welle discloses a "tagging" method. Applicant claims a "fingerprinting" method. The patent issued to Welle teaches a method by which a taggant composition is inserted into a product such that it can be retrospectively identified. The taggant composition includes multiple stable isotopes in both abundance and kind typically not naturally found in the product. The measurement of these isotopes is utilized to retroactively identify that product at a later time.

Tagging methods cannot be utilized in a number of instances. First, they cannot be used with products that have no taggant composition in the product such as products manufactured before these methods were known and manufactured without any taggant composition therein, and products in which taggant compositions are too expensive for use in identifying the product. Second, they cannot be utilized in products in which the purity or the toxicity of the product needs to be maintained as with food and pharmaceuticals. These products include food products, pharmaceuticals, and all other products in which varying the composition would render the composition less desirable, toxic or useless.

Applicant's method, using only naturally occurring stable isotopes, has the advantage over all methods utilizing a taggant composition such as disclosed by Welle, inasmuch as most taggant compositions are relatively expensive and the user of Applicant's method can ensure all that the initial purity of the product is maintained and that the product manufactured has not been altered.

Additionally, Applicant's method retrospectively identifies product by comparing the

product's own molecular structure not something added. The method of Welle retrospectively identifies the product by comparing additives to the product which typically are not molecularly bound to the product by chemical bonding, and thus, are loosely held in the product as a physical mixture or solution. All methods using taggant compositions including the method of the patent issued to Welle, retrospectively identify products, that by analogy, are like comparing steaks by analyzing the particular salt sprinkled on the steaks. In contrast, Applicant's method retrospectively identifies products by comparing the molecular structure of the product, i.e., the actual molecular structure of the protein of the steak, to known standards. Thus, in utilizing Applicant's method, additional assurances against unwanted interferences with the identification can be given to the user of Applicant's method.

Most of the prior art discloses tagging methods as much of the prior art has been developed in the field of geological exploration, prospecting in the petroleum industry, and medical studies in the health care industry. Tagging methods have been utilized to trace crude oil migration from one field to another. Tagging methods have also been used in the medical field in performing tracer studies such as drug metabolism and biomedical studies. None of this prior art teaches or suggests the retrospective identification of products by Applicant's method.

Similarly, none of the prior art using taggant compositions such as disclosed by Welle teaches or suggests Applicant's method. Rather, this art teaches away from using naturally occurring stable isotopes in retrospective identification of naturally occurring materials and materials produced by continuous processes, because crude oil from the same oil field but different spaced apart wells and oil refinery product of different calendar months have different amounts of naturally occurring stable isotopes due to the wide range of organic materials forming the crude oil. Similarly, batches of clam shells gathered off the coast of Ireland and

clam shells gathered off the coast of Connecticut may not be retrospectively distinguished by naturally occurring stable isotopes because of the lack of homogeneity of the two groups of clams shells. Tagging methods such as disclosed by Welle were developed as means of tracing large doses of artificially-added (exogenous) isotopic tracers which overwhelmed and masked the naturally occurring isotopic variations of the material.

Applicant has been the first to devise a method by which naturally occurring stable isotopes can be utilized to retrospectively identify products, trace these products through the manufacturing process, in the marketplace, and through various usages including potentially criminal or terroristic misusages of products or counterfeit products. Applicant's method applies only to batched products such as active pharmaceutical ingredients (API's), excipients of drug products, impurities in drug products, and other batched products. Naturally occurring products or products manufactured continuously cannot usually be retrospectively identified by Applicant's method as these products vary in time or location, depending upon formation process controls and raw materials, outside the scope of acceptable error. Both naturally occurring products and continuously manufactured products can be retrospectively identified by Applicant's method if those products are subsequently batched and the retrospective identification is between subsequently batched products. Applicant has provided a method by which naturally occurring stable isotopes may be used to retrospectively identify all batched products as long as they are initially or subsequently batched so as to be homogeneous within the error of the measurements.

Applicant's method is clearly usable to trace raw materials, ingredients, or synthetic intermediates through the manufacturing process, through the marketplace, and through the usage of all batch manufactured products, including pharmaceutical ingredients (API's),

excipients of drug products, impurities of drug products, raw materials and synthetic intermediates in drug products, and other batched products and between such products and their counterfeit products. Applicant's method can be used to retrospectively identify products which are batch manufactured, such as the pharmaceutical products above mentioned to distinguish those products from counterfeit products, to distinguish the same products manufactured by different manufacturers, to distinguish the same products manufactured from different raw materials and synthetic intermediates, and to distinguish the same products manufactured in different batches.

Applicant's method was sought by the Federal Bureau of Investigation in determining the origin of anthrax powder recently sent to U.S. Senators' Office Building following the events of September 11, 2001. It has also been employed for tracing illicit drugs. Applicant's method is also being seriously considered by international arson investigators and by the FBI in arson investigations to link accelerants found at fire scenes with batches of accelerants found on arson suspects or in suspected accelerant containers. Even through these materials are continuously manufactured at the refinery and the raw materials and the processing conditions at the refinery constantly change the isotopic concentrations, these materials are subsequently batched by mixing in small vessels such as accelerant containers such that Applicant's method utilizing naturally occurring stable isotopes can be used to link such evidentiary materials found at the scene retrospectively to an accelerant container.

Similarly, with regard to naturally occurring materials, such as clam shells on two different shorelines, the prior art would indicate that analysis of naturally occurring stable isotopes would not within the error desired allow Applicant's method to distinguish clams from one shoreline from clams from another shoreline. However, if the clam shells on the two

different shorelines were batched (sampled, pulverized to a microscopic scale, and mixed to be isotopically homogenous) identification of an unknown batch of clam shells could be linked to any one of the batches of clam shells by Applicant's method, but only to the shoreline if the sampling error was smaller than combined errors of batching and analysis.

So much depends upon the error of sampling and the precision desired in the identification, that Applicant's method was not discovered until useful quantitative estimates of precision for molecular isotopic measurements were devised. See "Quantitative Estimates of Precision for Molecular Isotopic Measurements" Jasper, J.P. *Rapid Communications in Mass Spectrometry*, 2001, 15, 1554-1557. Now, because known elements have a total of 224 naturally occurring stable isotopes, the error of using Applicant's method in comparing two batched products can be reduced to exceptionally low levels. Just using the 13 different naturally occurring stable isotopes in the common light elements of carbon, hydrogen, oxygen, nitrogen, and sulfur, specificities can be achieved which, in the analysis and retrospective identification of products with their sources, would be significantly greater than the precision achieved by DNA analysis (approximately 1 in 10 billion specificity). The specificity of the Applicant's method is proportional to the isotopic variation in a batched product induced by (i) the natural isotopic variations in its raw materials (thermodynamic variations), (ii) the anthropogenically-induced synthetic isotope variations (kinetic fractionations) and in the precision of the requisite isotopic measurements. No analysis of such accuracy is either intended nor could it plausibly be obtained with taggant materials and the Welle method.

The patent issued to Welle does not disclose or teach a method for identifying products limited to batched products, does not teach or suggest any method of identifying batched products utilizing naturally occurring stable isotopes, does not teach or suggest any method of

identifying batched products utilizing a mathematical or numerical array of concentrations from the analysis of naturally occurring stable isotopes as required by Applicant's method. The maximum number of isotopes disclosed by Welle is six, which is disclosed to produce one million unique codes at one percent precision. Applicant's method allows for the measurement of any of the naturally occurring stable isotopes of which there are a total of 224. Therefore, Applicant's method can be far more precise. For example, if one measures four isotope ratios each with a dynamic range of 1:100, one can be compounding those individual ranges to arrive at an estimated probability of $1:100^4$, or 1:100,000,000. See the discussion of error in Applicant's Specification on pages 22-19.

Whenever a taggant composition is used, the taggant composition is added to the product being tested. The taggant is usually intermixed with the product, and thus, is loosely held in the batch to be tested in a mixture or a solution rather than being chemically bonded to the product being compared. In contrast, Applicant utilizes naturally occurring stable isotopes within the matrix of the product itself. Welle does not teach any mathematical or numerical array of the isotopic concentrations of the product. Welle only compares the isotopic concentration ratios of specific isotopes of the taggant material mixed in with the product.

The patent issued to Brand et al does not materially add to the disclosure of the patent issued to Welle. The patent issued to Brand et al produces concentrations which are readable, but not machine readable. The patent issued to Brand et al also only discloses a process for the analysis of gaseous components by mass spectrometry.

Thus, neither the patent issued to Welle, nor the patent issued to Welle in view of Brand et al teaches or suggests or renders obvious a method utilizing a batched product for the concentration of a plurality of naturally occurring isotopes of at least one of the elements of at

least one of the compounds of said product, arranging the concentrations of the isotopes into a mathematical array, formulating the mathematical array into a readable form, or assembling the product information, indexing the product information in said readable form in an index, and maintaining the index and the product information as required by Claim 17 and Applicant's method.

The patent issued to Welle and the patent issued to Welle in view of Brand et al do not teach or suggest or render obvious an identification for a composition comprising an arrangement of empirical information derived from the analysis of a plurality of naturally occurring stable isotopes of at least one of the chemical elements of the composition, the arrangement comprising a numerical array of said imperical information in a readable form as required by Applicant's Claim 42 and method.

The patent issued to Welle and the patent issued to Welle in view of Brand et al do not teach or suggest or render obvious the method of analyzing a plurality of naturally occurring stable isotopes of a composition, deriving imperical information from said analyzing step, and arranging said imperical information into a numerical array as required by Applicant's Claim 45.

The patent issue to Welle and the patent issued to Welle in view of Brand et al do not teach or suggest or render obvious the identifying of a plurality of the naturally occurring stable isotopes of a composition analyzing the composition for the concentrations of a plurality of naturally occurring stable isotopes of the composition deriving imperical information from said analyzing step, and arranging imperical information into a numerical array as required by Applicant's Claim 50.

The patents issued to Welle and Welle in view of Brand et al do not teach or suggest or render obvious the providing of an objective identification for a batched product comprising the

steps of analyzing a batched product for the concentration of a plurality of naturally occurring stable isotopes of the product, arranging the concentrations of said isotopes into a mathematical array, formulating the mathematical array into a readable form, assembling product information with regard to said batched product, indexing said product information in said readable form to a description of said product thereby forming an index, and maintaining said index and said product information and said readable form as required by Claim 70.

The patents issued to Welle and Welle in view of Brand et al do not teach or suggest or render obvious the identification for a batched product comprising an arrangement of empirical information derived from an analysis of a plurality of naturally occurring stable isotopes of said batched product, said arrangement comprising a numerical array of said empirical information in a readable form as required by Claim 71, or an identification for a batched product comprising empirical information derived from analysis of a plurality of naturally occurring stable isotopes of a batched product, said empirical information being arranged in a numerical array, said numerical array being in a readable form, said readable form being comparable to the empirical information of said naturally occurring isotopes of unknown products whereby unknown products can be identified with and differentiated from known products as required by Claim 72.

The patents issued to Welle and Welle in view of Brand et al do not teach or suggest or render obvious the linking of an unknown composition to known compositions comprising the steps of analyzing a plurality of stable naturally occurring isotopes of a plurality of known compositions, deriving empirical information from said analyzing step of said known compositions, arranging said empirical information from said known compositions into numerical arrays, indexing said numerical arrays of said known compositions in a readable form to product information of said known compositions, analyzing a plurality of stable naturally

occurring isotopes of an unknown composition, deriving empirical information from said analyzing step performed on said unknown composition, arranging said empirical information from said unknown composition into a numerical array, comparing said numerical array of said unknown composition to said numerical arrays of said index, determining whether said numerical array of said unknown composition matches any of the numerical arrays of said index as required by Claim 73

The patents issued to Welle and Welle in view of Brand et al do not teach or suggest or render obvious the linking of an unknown composition to known compositions comprising the steps of analyzing a first plurality of stable naturally occurring isotopes of a second plurality of elements of a third plurality of batched products thereby generating a fourth plurality of isotopic data, listing said fourth plurality of isotopic data, listing identifications of said third plurality of batched products and linking said identifications with said isotopic data thereby forming an index, analyzing a fifth plurality of stable naturally occurring isotopes of a sixth plurality of elements of an unknown batched product thereby generating a seventh plurality of isotopic data, comparing said seventh plurality of isotopic data with said fourth plurality of isotopic data to identify said unknown product as one of said third plurality of batched products or to distinguish said unknown product from said third plurality of batched products, said fifth, sixth, and seventh plurality being less or equal in number to said first, second, and fourth plurality, respectively, and determining the precision of said comparing step by selecting said fifth plurality of stable naturally occurring isotopes of said unknown product as required by Claim 74.

Claims 18, 20, 21, 41, 49, 53, and 54 are each dependent upon Claim 17, thus each of these claims include all of the limitations of Claim 17 and are submitted to be patentable for the same reasons as reiterated above with regard to Claim 17. Claim 18 further requires:

“the step of measuring the concentration of one or more of said isotopes in a comparable substance and comparing the concentration of said one or more isotopes of said comparable substance with the concentrations of said mathematical array in readable form to identify said substance.”

Claim 20 further requires:

“said concentrations of isotopes are chosen from the group of isotopic concentrations consisting of concentrations of isotopes, concentrations of isotopes and their errors, and ratios of isotope concentrations, ratios of isotope concentrations and their errors and combinations thereof.”

Claim 21 further requires:

“said readable form is a machine readable form of said mathematical array, said product information is placed on a machine, said machine readable form being indexed to said product information.”

Claim 41 further requires:

“said mathematical array is chosen from the group of mathematical arrays consisting of a list of a plurality of concentrations, a list of a plurality of isotopic ratios, a list of a plurality of mathematical products of isotopic concentrations, a list of a plurality of mathematical products of isotopic ratios, groups of any such lists, groups of any such mathematical products, groups of any such ratios, groups of any such concentrations, mathematical products of any such concentrations plus or minus their error added, mathematical products of any such ratios plus or minus their error added, any such concentrations, ratios, lists, groups, and mathematical products in quadrature, isotopic ratios of any such mathematical products, ratios of said concentrations plus or minus their errors added, any of such concentrations plus or minus their errors added, factor analysis of any such concentrations, ratios, lists, groups, mathematical products and any determinants and combinations thereof.”

Claim 49 further requires:

“the step of increasing the composition of at least one of the plurality of naturally occurring stable isotopes of said composition, and analyzing the same as part of said analyzing step.”

Claim 53 further requires:

“said readable form is chosen from the group of readable forms consisting of serial numbers, bar codes, and other numerical and alphabetical indicia.”

Claim 54 further requires:

“the isotopes available are any of the 224 existing stable isotopes of known elements which have two or more isotopes.”

Claims 22 and 24 are dependent upon Claims 21 and 17, thus Claims 22 and 24 include all of the limitations of Claims 21 and 17 and are submitted to be patentable for the same reasons as reiterated above with regard to Claims 21 and 17. Claim 22 further requires:

“said product information may be displayed by identifying said machine readable form and indexing the same to said product information.”

Claim 24 further requires:

“measuring the concentration of said isotopes in a comparable substance, arranging said comparable substance concentrations into a mathematical array, and comparing the mathematical array of said comparable substance with said mathematical array of said product.”

Claim 23 is dependent upon Claims 22, 21, and 17, thus Claim 23 includes all of the limitations of Claims 22, 21, and 17 and is submitted to be patentable for the same reasons as reiterated above with regard to Claims 22, 21, and 17. Claim 23 further requires:

“said product information may be scrolled and/or downloaded or printed as desired.”

Claims 25-33, 36 and 37 are each dependent upon Claims 24, 21, and 17, thus Claims 25-33, 36 and 37 each include all of the limitations of Claims 24, 21 and 17 and are submitted to be patentable for the same reasons as reiterated above with regard to Claims 24, 21, and 17. Claim 25 further requires:

“said mathematical array includes ratios, concentrations, and products and said comparing step comprises comparing each of said ratios, concentrations or products step by step to identify said comparable substance within the error desired.”

Claim 26 further requires:

“said concentrations of isotopes are chosen from the group of isotopic concentrations consisting of concentrations of isotopes, concentrations of isotopes and their errors, and ratios of isotope concentrations, ratios of isotope concentrations and their errors.”

Claim 27 further requires:

“said readable form is chosen from the group of readable forms consisting of serial numbers, bar codes, and other numerical and alphabetical indicia.”

Claim 28 further requires:

“said mathematical array is chosen from the group of mathematical arrays consisting of a list of a plurality of concentrations, a list of a plurality of isotopic ratios, a list of a plurality of mathematical products of isotopic concentrations, a list of a plurality of mathematical products of isotopic ratios, groups of any such lists, groups of any such mathematical products, groups of any such ratios, groups of any such concentrations, mathematical products of any such concentrations plus or minus their error added, mathematical products of any such ratios plus or minus their error added, any such concentrations, ratios, lists, groups, and mathematical products in quadrature, isotopic ratios of any such mathematical products, ratios of said concentrations plus or minus their errors added, any of such concentrations plus or minus their errors added, factor analysis of any such concentrations, ratios, lists, groups, mathematical products and any determinants and combinations thereof.”

Claim 29 further requires:

“the isotopes available are any of the 224 existing stable isotopes of known elements which have two or more isotopes.”

Claim 30 further requires:

“said isotopes are of any of the 13 stable isotopes of the group of elements consisting of carbon, hydrogen, oxygen, nitrogen, sulfur

and combinations thereof.”

Claim 31 further requires:

“the error of identification is chosen by the mathematical array chosen, the number of concentrations of isotopes utilized in said array, and the portion of said array compared with the isotopic analysis of said unknown product.”

Claim 32 further requires:

“the batched product from which the concentrations of isotopes are analyzed and formed into a mathematical array is chosen from the group of batched products consisting of active pharmaceutical ingredients, excipients of drug products, impurities in drug products, raw materials and drug products, combustible fuels, additives to combustible fuels, environmental and natural occurring products, explosives and ammunition, gun powder, crude oil, petroleum distillates, hazardous waste, paper, ink, tire materials, paints and other coatings, and other synthetic materials.”

Claim 33 further requires:

“said concentrations of isotopes are chosen from the group of concentrations of isotopes consisting of bulk phase analysis and specific compound analysis.”

Claim 36 further requires:

“said analyses include nuclear magnetic resonance.”

Claim 37 further requires:

“said readable form is a machine readable form and said product information is stored in memory on a machine together with the index, said machine readable form, index and product information being interlinked, said machine readable form once identified through the index presents stored product information in displayed form.”

Claims 34 and 35 are each dependent upon Claims 33, 24, 21, and 17, thus Claims 34 and 35 each include all of the limitations of Claims 33, 24, 21, and 17 and are submitted to be

patentable for the same reasons as reiterated above with regard to Claims 33, 24, 21, and 17.

Claim 34 further requires:

“said bulk phase analysis includes off-line dual inlet isotope ratio mass spectrometry and on-line combustion coupled with high resolution isotope ratio monitoring/mass spectrometry.”

Claim 35 further requires:

“specific compound analysis includes gas chromatography coupled with irMS and liquid chromatography coupled with irMS.”

Claims 38-40 are each dependent upon Claims 37, 24, 21, and 17, thus Claims 38-40 each include all of the limitations of Claims 37, 24, 21, and 17 and are submitted to be patentable for the same reasons as reiterated above with regard to Claim 17. Claim 38 further requires:

“said product information may be scrolled through.”

Claim 39 further requires:

“said product information may be printed.”

Claim 40 further requires:

“said product information may be accessed through said index from said machine readable form of said mathematical array.”

Claims 43, 44, 55-59, 61, 65, and 66 are each dependent upon Claim 42, thus Claims 43, 44, 55-62, 65 and 66 each include all of the limitations of Claim 42 and are submitted to be patentable for the same reasons as reiterated above with regard to Claim 42. Claim 43 further requires:

“said empirical information further comprises the tolerable error of said analysis.”

Claim 44 further requires:

“said composition is a substance manufactured in an industry chosen from the group of industries consisting of the chemical, petroleum, pharmaceutical, biomedical, biochemical,

[homogeneous foodstuffs,] environmental [?], paint, explosive material and combustible fuel industries.”

Claim 55 further requires:

“said empirical information is chosen from the group of empirical information consisting of concentrations of isotopes, concentrations of isotopes and their errors, ratios of isotope concentrations, ratios of isotope concentrations and their errors and combinations thereof.”

Claim 56 further requires:

“said readable form is chosen from the group of readable forms consisting of serial numbers, bar codes, and other numerical and alphabetical indicia.”

Claim 57 further requires:

“said mathematical array is chosen from the group of mathematical arrays consisting of a list of a plurality of concentrations, a list of a plurality of isotopic ratios, a list of a plurality of mathematical products of isotopic concentrations, a list of a plurality of mathematical products of isotopic ratios, groups of any such lists, groups of any such mathematical products, groups of any such ratios, groups of any such concentrations, mathematical products of any such concentrations plus or minus their error added, mathematical products of any such ratios plus or minus their error added, any such concentrations, ratios, lists, groups, and mathematical products in quadrature, isotopic ratios of any such mathematical products, ratios of said concentrations plus or minus their errors added, any of such concentrations plus or minus their errors added, factor analysis of any such concentrations, ratios, lists, groups, mathematical products and any determinants and combinations thereof.”

Claim 58 further requires:

“said isotopes are any of the 224 existing stable isotopes of known elements which have two or more isotopes.”

Claim 59 further requires:

“said isotopes are of any of the 13 stable isotopes of the group of elements consisting of carbon, hydrogen, oxygen, nitrogen, sulfur and combinations thereof.”

Claim 61 further requires:

“the batched product from which the concentrations of isotopes are analyzed and formed into a mathematical array is chosen from the group of batched products consisting of active pharmaceutical ingredients, excipients of drug products, impurities in drug products, raw materials and drug products, combustible fuels, additives to combustible fuels, [homogeneous foodstuffs] environmental [?], natural occurring products, explosives products, ammunition, gun powder, crude oil, petroleum distillates, hazardous waste, paper, ink, tire materials, paints and other coatings, and other synthetic materials.”

Claim 65 further requires:

“said analyses include nuclear magnetic resonance.”

Claim 66 further requires:

“said readable form is a machine readable form that is comparable to other machine readable forms derived from the analysis of known products and their product information stored in memory on a machine together with an index, said machine readable forms, index, and product information being interlinked, said machine readable forms once identified through the index presents stored product information in displayed form.”

Claim 46 is dependent upon Claim 45, thus Claim 46 includes all of the limitations of Claim 45 and is submitted to be patentable for the same reasons as reiterated above with regard to Claim 45. Claim 46 further requires:

“said analyzing step comprises determining ratios of measured concentrations of two or more stable isotopes of said composition.”

Claim 47 is dependent upon Claims 46 and 45, thus Claim 47 includes all of the limitations of Claims 46 and 45 and is submitted to be patentable for the same reasons as reiterated above with regard to Claims 46 and 45. Claim 47 further requires:

“the steps of performing the method of Claim 46 for a plurality of known compositions, indexing said numerical arrays for said

known compositions in a readable form into an index linking said numerical arrays to product information for a plurality of known compositions, performing the method of Claim 46 for said unknown composition, comparing said numerical array for said unknown composition to said numerical arrays of said index, determining whether said numerical array for said unknown composition matches any of the numerical arrays contained in said index, and matching said numerical array of said unknown composition to the numerical array of a known composition in said index thereby identifying said unknown composition or distinguishing said unknown composition from said known compositions of said index.”

Claims 63 and 64 are each dependent upon Claims 62 and 42, thus Claims 63 and 64 each include all of the limitations of Claims 62 and 42 and are submitted to be patentable for the same reasons as reiterated above with regard to Claims 62 and 42. Claim 63 further requires:

“said bulk phase analysis includes off-line dual inlet isotope ratio mass spectrometry (irMS) and on-line combustion coupled with high resolution isotope ratio monitoring/mass spectrometry (irmMS).”

Claim 64 further requires:

“specific compound analysis includes gas chromatography coupled with irMS (irmGCMS) and liquid chromatography coupled with irMS (irmLCMS).”

Claims 67-69 are each dependent upon Claim 42, thus Claims 67-69 each include all of the limitations of Claim 42 and are submitted to be patentable for the same reasons as reiterated above with regard to Claim 42. Claim 67 further requires:

“said product information may be scrolled through.”

Claim 68 further requires:

“said product information may be printed.”

Claim 69 further requires:

“said product information may be accessed through said index from said machine readable form of said mathematical array.”

Claims 75-78, 81-84, and 86-89 are each dependent upon Claim 74, thus, Claims 75-78, 81-84, and 86-89 each include all of the limitations of Claim 74 and are submitted to be allowable for the same reasons as reiterated above with regard to Claim 74. Claim 75 further requires:

“said analyzing said first plurality and fifth plurality include analyses chosen from the group of analyses consisting of bulk phase analyses including offline dual inlet isotope ratio mass spectrometry (IRMS) and online combustion coupled with high resolution isotope ratio monitoring/mass spectrometry (IRMS), NMR, and specific compound analyses including gas chromatography coupled with IRMS (IRMGCMS) and liquid chromatography coupled with IRMS (IRMLCMS).”

Claim 76 further requires:

“said stable naturally occurring isotopes include any of the 224 existing stable isotopes of known elements that have two or more isotopes.”

Claim 77 further requires:

“said stable naturally occurring isotopes are any of the 13 stable isotopes of the group of elements consisting of carbon, hydrogen, oxygen, nitrogen, sulfur and combinations thereof.”

Claim 78 further requires:

“said fourth plurality of isotopic data are arranged in a plurality of mathematical arrays being presented in a readable form.”

Claim 81 further requires:

“said identification listing results in a list of physical properties of said third plurality of batched products.”

Claim 82 further requires:

“said identification listing results in a list of chemical properties of said third plurality of batched products.”

Claim 83 further requires:

“said unknown batched product is a sample of a product larger in volume of said sample, and said sampling of said larger in volume products is more precise than the precision of said comparing step.”

Claim 84 further requires:

“said analyses of said analyzing steps each have a dynamic range equal to the observed range divided by the 1-sigma standard deviation.”

Claim 86 further requires:

“the specificity of said comparing step using analyses of C^{13} , N^{15} , O^{18} and H^3 is determined by the following equation: Specificity = $(1\sigma - \delta^{13}C/\Delta\delta^{13}C) * (1\sigma - \delta^{15}N/\Delta\delta^{15}N) * (1\sigma - \delta^{18}O/\Delta\delta^{18}O) * (1\sigma - \delta D/\Delta\delta D)$.”

Claim 87 further requires:

“the specificity of said comparing step is inversely proportional to the product of the dynamic ranges of each isotopic analysis undertaken of said unknown batched product.”

Claim 88 further requires:

“the precision of said comparing step is increased by compounding the precisions of said seventh plurality of isotopic data.”

Claim 89 further requires:

“the predicted degree of specificity of said comparing step is inversely proportional to the product of the dynamic ranges for each isotopic analyses undertaken in analyzing said fifth plurality of stable naturally occurring isotopes of a sixth plurality of elements of said unknown product.”

Claims 79 and 80 are each dependent upon Claims 78 and 74, thus Claims 79 and 80 each include all of the limitations of Claims 78 and 74 and are submitted to be allowable for the same reasons as reiterated above with regard to Claims 78 and 74. Claim 79 further requires:

“said readable form is chosen from the group of readable forms consisting of serial numbers, bar codes and other numerical and alphabetical indicia.”

Claim 80 further requires:

“said fourth plurality listing step results in a list of machine readable arrays.”

Claim 85 and 90 are each dependent upon Claims 84 and 74, thus Claims 85 and 90 each include all of the limitations of Claims 84 and 74 and are submitted to be allowable for the same reasons as reiterated above with regard to Claims 78 and 74. Claim 85 further requires:

“the precision of each of said analyses is the 1-sigma standard deviation of the analysis performed divided by the square root of the number of observations of said analysis.”

Claim 90 further requires:

“the dynamic range is the range of values expected for an analysis divided by the 1-sigma standard deviation of that analysis.”

For all of the reasons above given Applicant respectfully submits that each of the claims of the application, as amended, patentably distinguish Applicant's invention from the patents cited and/or applied by the Examiner, whether taken alone or in combination with each other. Applicant respectfully solicits a prompt issuance of a Notice of Allowance.

Respectfully submitted,

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Reg. No. 22,162